DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-565/S-009

ESI Lederle
2 Esterbrook Lane
Cherry Hill, NJ 08003

Attention: J. Barton Kalis
Manager, Regulatory Affairs

Dear Mr. Kalis:

Please refer to your supplemental new drug application dated August 25, 2000, received August 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duramorph® (morphine sulfate injection, USP) and Infumorph® (morphine sulfate sterile solution).

This supplemental new drug application provides for the additon of a Geriatric Use subsection to comply with 21 CFR §201.57, changes to comply with the Food and Drug Modernization Act of 1997, and changes to the Adverse Reactions sections of the package insert.

We have completed the review of this supplemental application and it is approved with the minor editorial revisions listed below, effective on the date of this letter.

DURAMORPH and INFUMORPH:

GERIATIC USE
The pharmacodynamic effects of neuraxial morphine in the elderly are more variable than in the younger population.

DURAMORPH:

INTRAVENOUS ADMINISTRATION
Geriatric Use: Administer with extreme caution (see PRECAUTIONS)

EPIDURAL ADMINISTRATION/Epidural Adult Dosage:
Geriatric Use: Administer with extreme caution. (See PRECAUTIONS.)

INTRATHECAL ADMINISTRATION/Intrathecal Adult Dosage:
Geriatric Use: Administer with extreme caution. (See PRECAUTIONS.)

INFUMORPH:

DOSAGE AND ADMINISTRATION
Intrathecal dosage:
Geriatric Use: Administer with extreme caution. (See PRECAUTIONS.)
Epidural dosage:
Geriatric Use: Administer with extreme caution. (See PRECAUTIONS.)

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted August 25, 2000). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-565/S-009." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Cynthia McCormick

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